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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,968	07/28/2003	Michael Porat	03128CIP	4080
23338 7590 03/08/2007 DENNISON, SCHULTZ & MACDONALD 1727 KING STREET SUITE 105 ALEXANDRIA, VA 22314			EXAMINER BETTON, TIMOTHY E	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/08/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/627,968

Applicant(s)

PORAT, MICHAEL

Examiner

Timothy E. Betton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3 sheets.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/ Restriction

Applicant's election with traverse of election of species requirement in the reply filed on 11 October 2006 is acknowledged.

The traversal is on the ground(s) that Applicant believes that the requested election is overly restrictive. Thus, Applicant does not believe the difference between chlorhexidine gluconate and chlorhexidine digluconate to be significant, and further does not believe the difference between methyl paraben and propyl paraben to be significant. For example, these parabens are typically used in combination in compositions.

Applicant's traverse, however, is not found persuasive.

For the purposes of facilitating examination, a specific and exact disclosed component of a genus thereof is required. Whether the differences are deemed to be significant or not, the requirement directed toward selecting a specific component or derivative thereof for examination is necessary and therefore proper.

Further, Applicant requests that species (B1) and (B2) and species (C1) and (C2) be considered to be elected. This request is denied because applicant's traversal argument is an allegation without factual support and therefore non-persuasive regarding combining, as elected, species with distinct chemical structures being either not significant not used together

For the reasons stated above, by requirement applicant must select one exact and specific species for examination.

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The election of (A1), (B2), and (C1) is acknowledged with the traversal argument and found non-persuasive.

This election is therefore made FINAL.

Status of the Claims

Instant claims 1-12 and 14 are pending for prosecution on the merits.

Claim Rejections 35 USC § 112, 1ST Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling as a prophylactic and contraceptive (spermicidal activity), it, however, does not reasonably provide enablement for the prevention or inhibitor of the HIV virus and/or other related conditions. The Specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As stated in MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue."

In re Wands, set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph:

1. The nature of the invention;
2. The state of the prior art;
3. The predictability or lack thereof in the art;
4. The amount of direction or guidance present;
5. The presence or absence of working examples;
6. The breadth of the claims;
7. The quantity of experimentation needed; and
8. The level of the skill in the art.

The nature of the invention; The state of the prior art; The predictability or lack thereof in the art;

The nature of the invention is complex. The instant invention is drawn toward a practicing prophylactic lubricant composition for use during sexual relations comprising a lubricant and an effective amount of a spermicidal antiseptic active against HIV and other viruses.

The state of the prior art is drawn toward prophylactic devices such as condoms and diaphragms as moderately effective contraceptives. Lubricants are generally associated as with use with above prophylactic devices, i.e., condoms with spermicidal lubricant. Gels and Lubricants indicated for use without prophylactics are generally used to reduce friction during sexual intercourse and/or are provided with an active ingredient within the lubricant, which is indicated to decrease the chances of contraception.

The lack of predictability is high due to a variance of factors. The active agent indicated for use in preventing the HIV virus may not be as effective against a more

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resistant strain of the HIV virus in a patient. in the occasion of a compromise in the integrity of the epidermis, i.e. orifice, open wound, lesions, instant specification should contain determinative evidence of the rate of therapeutic success. The level of predictability continues to face challenges in lieu of the plethora of anti-HIV agents on the market for therapeutic use. The bioavailability comparison between an agent given by mouth in comparison to an agent applied topically also makes the level of unpredictability significantly high. Porat (USPN 6,624,198 B1) teach maximum safety via use of condom or diaphragm in concomitance with the prophylactic lubricant on the occasion of a compromise in the device used (column 6, lines 30-40). Thus, there is the suggestion that from said referenced patent that a level of unpredictability may exist due to varying combinations of usage.

The amount of direction or guidance present; The presence or absence of working examples; The breadth of the claims;

The specification does not provide adequate direction or guidance as to enablement of instant invention in the prevention of HIV and other related viruses. Further, the specification discloses insufficient and/or fails to disclose pertinent studies drawn to the enablement of the prophylactic lubricant composition in the prevention of the HIV virus and all related viruses.

The breadth of the claims contains subject matter of which the specification does not sufficiently encompass the metes and bounds of the intended invention.

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**The quantity of experimentation needed; and
The level of the skill in the art**

The quantity of continued experimentation in the art is needed. The multiplicity of susceptibilities, properties, and characteristics shared between both patient and a practicing prophylactic composition lubricant is high.

The level of skill in the art is such that one of ordinary skill in the pertinent art would instantly recognize the necessity for a determined quantity of experimentation to reasonably expect enablement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-12 and 14 are rejected under the judicially created doctrine of obviousness-type double-patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6624198 (Porat). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and Porat (USPN 6624198) claim a prophylactic lubricating/spermicidal composition for its use in sexual relations, including prevention of infection by HIV and other viruses.

The difference between the claimed invention of the instant application and the referenced patent 6624198 is that said patent discloses a practicing method with said composition, while the claimed invention of the instant application discloses said composition. However, it would be obvious to one of ordinary skill in the art at the time the invention was made to select a species of the genus, observe similar properties and therapeutic effects and therefore use (as in a method for use).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H. Marschel 3/4/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

TEB